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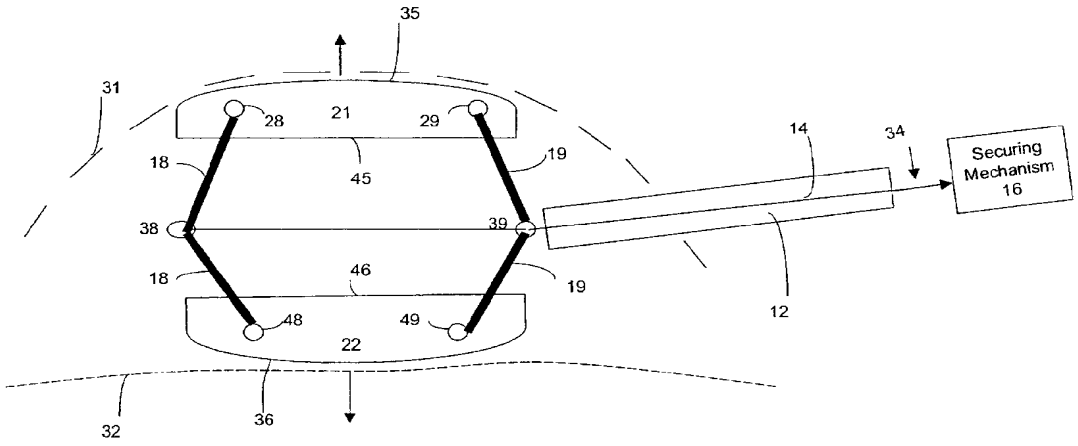
(54) Title: ENDOSCOPIC STABILIZATION DEVICE



DEPLOYED CONFIGUATION

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(57) Abstract: An endoscopic stabilization device is provided. The device includes first and second support elements positioned opposite each other, a plurality of linkages, each linkage including a first end portion attached to the first support element and a second end portion attached to the second support element; and a cable operatively attached to the linkages at a first end to allow a user to pull a second end of the cable to move the first support element in a direction away from the second support element. Methods of using the device to stabilize and immobilize components in the body are also provided.

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ENDOSCOPIC STABILIZATION DEVICE

FIELD OF THE INVENTION

This invention relates to devices that are capable of supporting or compressing an organ, such as the heart, and of exposing a given area of tissue to permit a surgical procedure to be performed in an area where minimal invasive procedures are desired. In particular, the invention relates to an endoscopic device that is capable of separating, exposing, stabilizing and supporting different tissues, organs and viscera so that appropriate areas of tissue are exposed.

BACKGROUND OF THE INVENTION

Surgery on certain areas of an organ such as the heart is difficult because the organ is not easily accessible. In particular, as endoscopic surgery becomes more prevalent, the area accessible to surgery will become even more localized. The need for supporting the organ and presenting the appropriate surface for surgery will be even greater. For example, the heart is located beneath the chest wall and surrounded by a variety of other body organs and components, which makes it difficult to access. In addition, the heart continually moves (beats). In order to perform surgery on a particular area of the heart, the heart must be stopped completely or at least stopped in the area of surgery.

Typically, the chest wall is opened and the heart stopped completely for the time it takes the surgery to be performed (open heart surgery.) In some cases, the heart is stopped in particular areas using a device such as the Octopus Cardiac Tissue Stabilizer described in U.S. Patent No. 5,927,284 to Medtronic. Surgery is then performed in the stopped area while the rest of the heart continues to beat (beating heart surgery). In an endoscopic version of heart surgery, the chest wall would not be opened but rather stab wounds would be made in the chest cavity at strategic points and the surgery performed while the heart remains behind the sternum.

One difficulty in this type of surgery is separating the heart sufficiently from other components within the chest cavity including the sternum and ribs. Another difficulty is stopping the heart in an area to perform the surgery. Although existing devices could be

used to immobilize the heart for such surgery, any additional device used must be inserted into the relatively small chest cavity, taking up space.

It would be desirable therefore to have a device that separates the heart sufficiently from other tissues, organs and rib structures to present an area of the heart for surgery without obscuring that area.

Furthermore it would be desirable if the device could also support the heart, bracing it while causing little distress to the heart.

Additionally, it would be desirable if the device could be capable of immobilizing portions of the heart for surgery, thereby eliminating the need for an additional immobilization device, particularly in an endoscopic surgical procedure.

SUMMARY OF THE INVENTION

One aspect of the invention provides an endoscopic stabilization apparatus that includes first and second support elements positioned opposite each other, a plurality of linkages attached to the support elements and a cable attached to the linkages to allow a user to pull the cable to move the first support element in a direction away from the second support element. The apparatus may include a handle portion with an opening for the cable. The apparatus may include a securing mechanism operatively attached to an end of the cable. The first end of the linkages may be attached adjacent an edge of the first support element and the second end of each linkage may be attached adjacent an edge of the second support element. The midpoint of each linkage may also be attached to a connecting bar. The cable is attached in a fixed or a slidable manner at the midpoint of at least one of the linkages. The support elements may be pads arranged directly opposite each other. The support elements may be textured. The support elements may include suction elements. The support elements may return to a collapsed position when the cable is not in tension. The apparatus may be secured with a thumbscrew mechanism.

Another aspect of the invention provides a method of bracing an organ. An endoscopic support apparatus is provided. The apparatus is positioned in a collapsed configuration and inserted into a body cavity. Movement of the cable separates the support elements. At least one of the support elements is then braced against a component

within the body cavity. The apparatus may then be secured in a desired configuration. The apparatus may include suction elements that are used to grasp the component within the body cavity.

Another aspect of the invention provides a method of stopping movement of a heart. An endoscopic support apparatus is provided. The apparatus is positioned in a collapsed configuration and inserted into a chest cavity. Movement of the cable separates the support elements. One of the support elements is then braced against an area of chest wall the other is braced against an area of the heart with sufficient pressure to stop movement of the heart. The apparatus may then be secured in a desired configuration. The apparatus may include suction elements that are used to grasp the chest wall and/or the heart.

Another aspect of the invention provides a support apparatus for separating an organ from a chest wall. The apparatus includes an elongated handle including an opening formed therein, a cable received in the handle opening, first and second support elements positioned opposite each other, a first linkage connected adjacent a first end of each of the first and second support elements, a midpoint of the first linkage connected to the cable, a second linkage connected adjacent a second end of each of the first and second support element and a midpoint of the second linkage connected to the cable. The cable is pulled to move the first and second support elements away from each other to separate the organ from the chest wall. The cable is attached in a fixed manner at the midpoint of the first linkage and in a slidable manner at the midpoint of the second linkage. The apparatus may include a securing mechanism attached to an end of the cable.

The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of an endoscopic stabilization device in a collapsed position in accordance with the present invention;

FIG. 2 is a side view of an endoscopic stabilization device in an expanded position in accordance with the present invention braced within a body cavity; and

FIG.3 is a front view of another embodiment of an endoscopic stabilization in an expanded position in accordance with the present invention braced within a body cavity.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

FIG. 1 shows an endoscopic stabilization device in accordance with the present invention in a collapsed configuration. Endoscopic device **10** comprises two support pads **21**, **22** arranged one above the other and attached by a connecting cable **14** and an arrangement of rigid linkages **18**, **19**. The distal end of the connecting cable **14** may be connected to the pad and linkage arrangement. The proximal end of the connecting cable may be enclosed within a hollow handle **12**.

The handle **12** of endoscopic device **10** may be a hollow tube of relatively small diameter. Preferably, handle **12** may be a size and diameter insertable within an endoscopic port. For use in a standard endoscopic procedure, for example, the diameter of handle **12** may fall within the range of 2-10 mm. Alternatively, the end of handle **12** that is inserted into the body cavity may be of a smaller diameter than the other end of the handle left outside the body. The diameter of handle **12** may preferably be only slightly larger than the diameter of connecting cable **14**.

While it is preferable that handle **12** be circular in cross section, thereby occupying a minimal area, it is contemplated that handle may be square, rectangular or any other cross section that is desired or convenient. Preferably handle **12** may be made of a biocompatible material such as stainless steel, plastic or a combination of the two. Preferably, a biocompatible material prompts little allergenic response from the patient's body and is resistant to corrosion from being placed within the patient's body. Furthermore, the biocompatible material preferably does not cause any additional stress to

the patient's body, for example, it does not scrape detrimentally against any elements within the surgical cavity. Handle **12** may be malleable. Optionally, handle **12** may have other components attached to lend convenience and utility to the handle, for example, a grip or trigger component.

Connecting cable **14** may be enclosed within handle **12** such that the two ends of cable **14** protrude from handle **12**. The length of connecting cable **14** may be any suitable length for insertion into a body cavity. Cable **14** may have a distal end that is inserted into a body cavity and a proximal end that may be attached to a securing mechanism **16**, as seen in **FIG. 2**. Cable **14** may be made of a biocompatible material as described above. Cable **14** may be a braided metal fiber. Cable **14** may also be a stainless steel cable. Cable **14** is preferably flexible but capable of tensioning without breaking.

At its distal end connecting cable **14** may be connected to an arrangement of rigid linkages **18, 19**. These rigid linkages **18, 19** may be disposed between an upper support pad **21** and a lower support pad **22**. "Upper" and "lower" are used herein for reference to the figures, and it is contemplated that the device may be used in various orientations. These linkages may be made of stainless steel. Linkages **18, 19** may also be made of a rigid thermoplastic. Alternatively, linkages **18, 19** may be made out of any suitably strong, suitably rigid biocompatible material as described above.

Preferably, two rigid linkages **18, 19** may be disposed between pads **21, 22**, although the number and configuration of linkages may vary. Linkage **18** may preferably comprise an upper and lower component. "Upper" and "lower" are used herein for reference to the figures, and it is contemplated that the device may be used in various orientations. The upper component of linkage **18** may be attached to upper pad **21** at point **28** and to connecting cable **14** at point **38**. The lower component of linkage **18** may be attached to lower pad **22** at point **48** and to connecting cable **14** at point **38**. Upper and lower components of linkage **18** may pivot at point **38**. Linkage **19** may preferably be structured in the same manner as linkage **18**. For example, in **FIG. 1**, linkage **19** is attached to upper pad **21** at point **29**, to connecting cable **14** at point **39** and to lower pad **22** at point **49**. Connecting cable **14** may preferably be connected to pivot point **38** in a

fixed manner. Connecting cable **14** may preferably be connected to pivot point **39** in a slidable manner.

Upper and lower support pads **21**, **22** may be made from biocompatible material. The pads **21**, **22** may be made from materials including, for example, thermoplastic or thermosetting materials if it is desired to make endoscopic device **10** disposable. Upper and lowers support pads **21**, **22** may be, for example, 5-10 mm in width and 20-30 mm in length for convenient insertion through an endoscopic port. The support pads **21**, **22** may be made in any size that is convenient depending upon the need.

Additionally, support pads **21**, **22** may be made of material to improve their bracing and grasping properties. For example, pads **21**, **22** may be made of any material that grasps organ surfaces well, such as for example, biocompatible rubber. Alternatively, pads **21**, **22** may be covered or coated with any material that grasps organ surfaces well. Additionally, support pads **21**, **22** or the covering may be textured to better grip an organ surface. Support pads **21**, **22** may also incorporate elements that would enable better grasping, such as for example, suction elements.

FIG. 2 shows an endoscopic stabilization device in accordance with the present invention in an expanded configuration within the chest cavity. Rigid linkages **18**, **19** are shown connecting upper support pad **21** to lower support pad **22**. Connecting cable **14** may be connected to linkage **18** at midpoint **38** and to linkage **19** at midpoint **39**.

In use, support device **10** may be inserted into a body cavity, for example, the chest cavity, in the collapsed configuration of **FIG. 1**. Insertion may be through a cannula or trocar (not shown). When device **10** is in a collapsed configuration, the support pads **21**, **22** may present a streamlined device that permits a nontraumatic entry of the device into the body.

Additionally, to facilitate insertion, device **10** may be covered with flexible covering **40** as shown in **FIG. 1**. This membrane **40** may be made of a flexible biocompatible material such as rubber or polyurethane. Covering **40** may serve to cover any protruding parts of device **10** during insertion into the body cavity. Covering **40** may also serve to help device **10** better conform to and grip the organ surface. Alternatively, device **10** may be inserted without any covering, as seen in **FIG. 2**.

The surgeon may then use handle **12** to maneuver the support pads **21**, **22** into position within the body cavity. At the appropriate location, the surgeon may spread support pads **21**, **22** so that upper pad **21** is braced against one element within the cavity and lower pad **22** is braced against a second element within the cavity. For example, in the embodiment shown in **FIG. 2**, pad **21** may be braced against chest wall **31** and pad **22** may be braced against a surface of the heart **32**. As shown in **FIG. 2**, upper support pad **21** may have an outer face **35** that meets the surface of the organ being braced and an inner face **45** that meets lower support pad **22**. Lower support pad **22** may have an outer face **36** that meets the surface of the organ being braced and an inner face **46** that meets upper support pad **21**.

The pads **21**, **22** may be spread apart by pulling on connecting cable **14**. When the surgeon pulls on connecting cable **14**, midpoint **39** may be pulled towards handle **12**. Meanwhile, midpoint **38** may move closer to midpoint **39**. As midpoint **38** moves closer to midpoint **39**, the upper and lower components of rigid linkage **18** may be forced apart, thereby forcing upper pad **21** away from lower pad **22**. Meanwhile, the tension of midpoint **39** against handle **12** may also force the upper and lower components of rigid linkage **19** apart, thereby forcing upper pad **21** away from lower pad **22**. Handle **12** may act as a bracing element for midpoint **39**. Alternatively, midpoint **39** may be braced against another suitable bracing element. Rigid linkage **19** may also be made suitably rigid to maintain a braced position for midpoint **39**. Alternatively, rigid linkage **19** may incorporate a bracing mechanism to maintain a braced position for midpoint **39.**

In order to tension connecting cable **14** so that pads **21**, **22** are at a desired position, the proximal end of cable **14** may be attached to a securing mechanism **16**. Securing mechanism **16** may be attached to handle **12** or it may be a separate member. This holds stabilization and support device **10** in the desired position for stabilizing an organ such as the heart **32** against the chest wall **31**. Securing mechanism **16** may be, for example, a thumbscrew mechanism, which may be twisted to pull the connecting cable **14**. Securing mechanism **16** may also be a rack and pinion mechanism, which may be turned to pull the connecting cable **14**. Connecting cable **14** may be pulled manually until a desired tension

is reached and then attached at its proximal end to a securing mechanism such as a support plate or a support pin. Securing mechanism **16** may be any suitable means for holding pads **21**, **22** in the desired expanded position.

In one method of employing stabilization and support device **10**, cable **14** is pulled until the position of pads **21**, **22** applies sufficient pressure to immobilize an area of the organ being braced. This is particularly desirable because it immobilizes the organ without need for inserting an additional immobilization device. For example, when pads **21**, **22** are braced in such a manner against heart **32**, a nearby area of heart tissue may be immobilized so that surgery may be performed. No further device may be needed for this immobilization. In another embodiment, two devices **10** are used to brace the heart in two locations. The area between the two locations may then be immobilized so that surgery may be performed.

FIG. 3 shows a front view of an alternate embodiment of an endoscopic stabilization device **310** in accordance with the present invention. In this embodiment, two rigid linkages **18** and **318** are disposed towards a front end of device **10** and two additional linkages **19** and **319** are disposed towards a back end of device **10**. Linkages **18** and **318** may be connected by bar **337**, which in turn connects to cable **14** (shown in shadow). Bar **337** serves as a pivot point for linkages **18** and **318**. Linkages **19** and **319** may also be connected by a similar bar **347**. Bar **347** may also serve as a pivot point for linkages **19** and **319**.

In use, pads **21**, **22** are spread apart by pulling on connecting cable **14**. When the surgeon pulls on connecting cable **14**, bar **347** is pulled towards handle **12**. Meanwhile, bar **337** moves closer to bar **347**. As bar **337** moves closer to bar **347**, the upper components of rigid linkages **18**, **318** are forced away from the lower components of rigid linkages **18**, **318**, thereby forcing upper pad **21** away from lower pad **22**. Meanwhile, the tension of bar **47** against handle **12** also forces the upper components of rigid linkages **19**, **319** away from the lower components of rigid linkages **19**, **319**, thereby forcing upper pad **21** away from lower pad **22**. The proximal end of cable **14** may be attached to a securing mechanism **16** as described above to hold stabilization and support device **10** in a desired position.

FIG. 3 also shows suction elements **350** disposed on pads **21, 22**. These elements may allow better gripping of organ surfaces such as chest wall **31** and heart **32**. It is contemplated that if support pads **21, 22** incorporate suction elements, a flexible suction tube that may provide suction to the suction elements may also serve as connecting cable **14**. Alternatively, a separate suction tube or tubes may be incorporated into handle **12**.

As noted above, the endoscopic device **10** of the present invention can be used in an endoscopic heart surgery. It is contemplated that the stabilization and support device of the invention may be used in immobilization or bracing of other organs such as, for example, the liver, the diaphragm or the spleen.

It should be appreciated that the embodiments described above are to be considered in all respects only illustrative and not restrictive. The scope of the invention is indicated by the following claims rather than by the foregoing description. All changes that come within the meaning and range of equivalents are to be embraced within their scope.

I CLAIM:

1. An endoscopic stabilization apparatus comprising:

first and second support elements positioned opposite each other;

a plurality of linkages, each linkage including a first end portion attached to the first support element and a second end portion attached to the second support element; and

a cable operatively attached to the linkages at a first end to allow a user to pull a second end of the cable to move the first support element in a direction away from the second support element.

2. The apparatus of claim 1 further comprising:

a handle portion, the handle portion including an opening formed therein to receive the cable.

3. The apparatus of claim 1 further comprising:

a securing mechanism operatively attached to an end of the cable.

4. The apparatus of claim 1 wherein the plurality of linkages comprises two linkages, the first end portion of each linkage attached adjacent an edge of the first support element and the second end portion of each linkage attached adjacent an edge of the second support element.

5. The apparatus of claim 1 wherein the plurality of linkages comprises at least four linkages, the first end portion of each linkage attached adjacent an edge of the first support element and the second end portion of each linkage attached adjacent an edge of the second support element and the midpoint of each linkage operatively attached to a connecting bar.

6. The apparatus of claim 1 wherein the cable is attached in a fixed manner at a midpoint of at least one of the linkages.

7. The apparatus of claim 1 wherein the cable is attached in a slidable manner at a midpoint of at least one of the linkages.

8. The apparatus of claim 1 wherein the cable is attached in a fixed manner at a first midpoint of a first linkage and in a slidable manner at a second midpoint of a second linkage.

9. The apparatus of claim 1 wherein the first and second support elements comprise pads.

10. The apparatus of claim 1 wherein the first and second support elements are positioned directly opposite each other.

11. The apparatus of claim 1 wherein the first and second support elements are textured.

12. The apparatus of claim 1 further comprising a plurality of suction elements operatively attached to a face of each of the first and second support elements.

13. The apparatus of claim 1 wherein the first and second support elements return to a collapsed position when the cable is not in tension.

14. The apparatus of claim 1 wherein the securing mechanism is a thumbscrew mechanism.

15. A method of bracing an organ comprising:

providing an endoscopic support apparatus comprising first and second support elements positioned opposite each other, a plurality of linkages, each linkage including a first end portion attached to the first support element and a second end portion attached to the second support element; and a cable operatively attached to the linkages at a first end to allow a user to pull a second end of the cable to move the first support element in a direction away from the second support element;

positioning the apparatus in a collapsed configuration;

inserting the apparatus in a collapsed configuration into a body cavity;

separating the support elements by movement of the cable; and

bracing at least one of the support elements against a component within the body cavity.

16. The method of claim 15 further comprising:

securing the apparatus into a desired configuration.

17. The method of claim 15, wherein the support elements are textured.

18. The method of claim 15, wherein the support elements have a face with a plurality of suction elements operatively attached to the face, further comprising:

grasping the component within the body cavity with at least one of the suction elements.

19. A method of stopping movement of a heart comprising:

providing an endoscopic support apparatus comprising first and second support elements positioned opposite each other, a plurality of linkages, each linkage including a first end portion attached to the first support element and a second end portion attached to the second support element; and a cable operatively attached to the linkages at a first end to allow a user to pull a second end of the cable to move the first support element in a direction away from the second support element;

positioning the apparatus in a collapsed configuration;

inserting the apparatus in a collapsed configuration into a chest cavity;

separating the support elements by movement of the cable;

bracing the first support element against an area of chest wall; and

bracing the second support element against an area of the heart with sufficient pressure to stop movement of the heart.

20. The method of claim 19 further comprising:

securing the apparatus into a desired configuration.

21. The method of claim 19 wherein the support elements are textured.

22. The method of claim 19, wherein the support elements have a face with a plurality of suction elements operatively attached to the face, further comprising:

grasping the chest wall with at least one of the suction elements.

23. The method of claim 19, wherein the support elements have a face with a plurality of suction elements operatively attached to the face, further comprising:

grasping the heart with at least one of the suction elements.

24. A support apparatus for separating an organ from a chest wall, comprising:

an elongated handle including an opening formed therein;

a cable received in the handle opening;

first and second support elements positioned opposite each other;

a first linkage connected adjacent a first end of each of the first and second support elements;

a midpoint of the first linkage connected to the cable;

a second linkage connected adjacent a second end of each of the first and second support element; and

a midpoint of the second linkage connected to the cable;

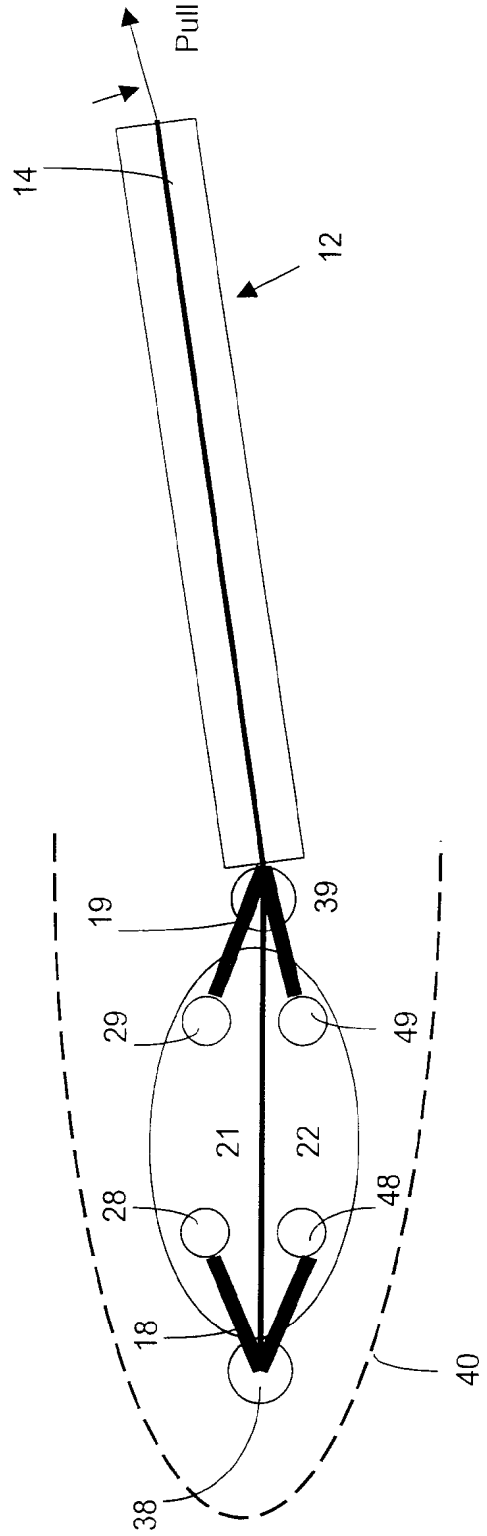
wherein the cable is pulled to move the first and second support elements away from each other to separate the organ from the chest wall.

25. The apparatus of claim 24 wherein the cable is attached in a fixed manner at the midpoint of the first linkage and in a slidable manner at the midpoint of the second linkage.

26. The apparatus of claim 24 further comprising:

a securing mechanism operatively attached to an end of the cable.

FIG. 1



DEPLOYMENT CONFIGURATION

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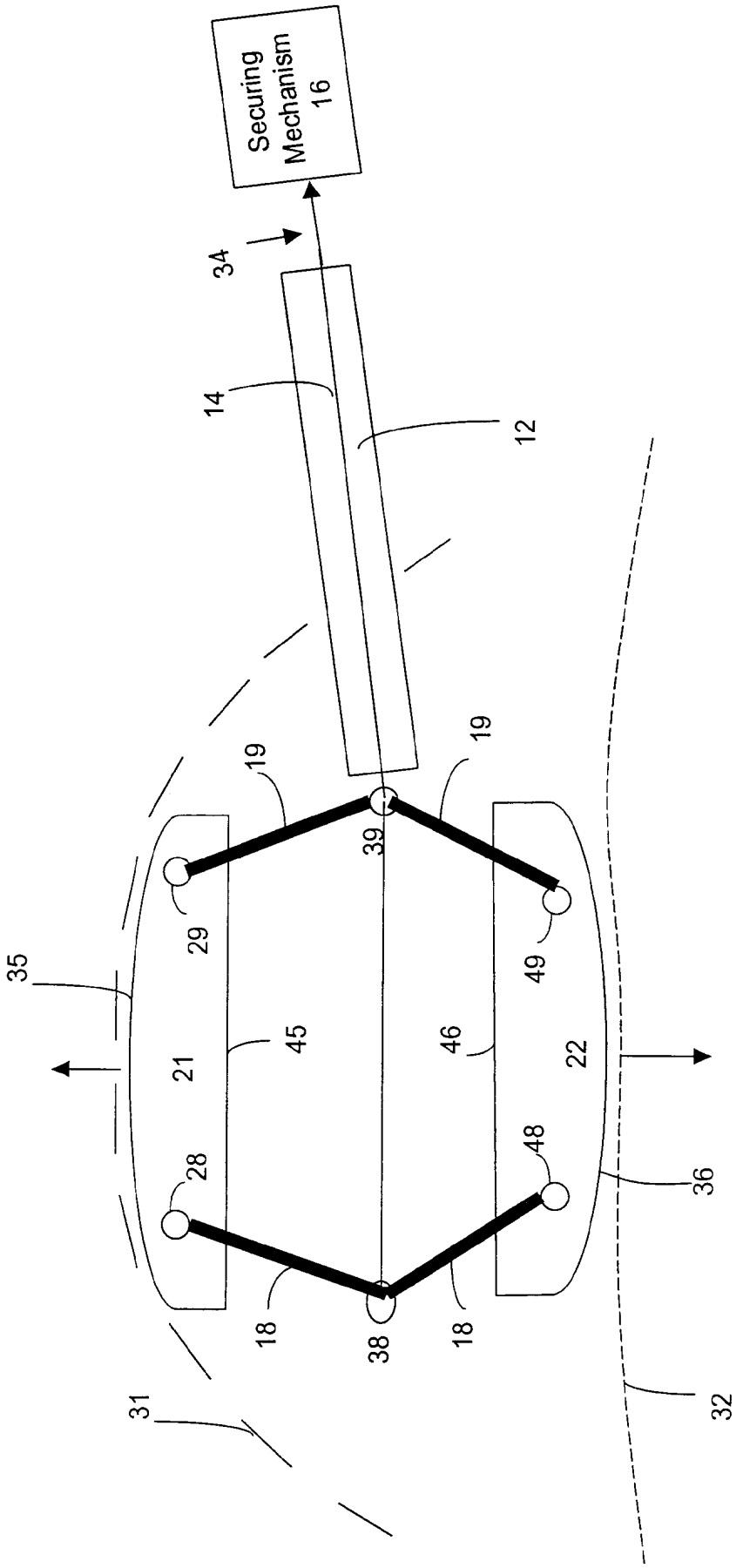
FIG. 2


Securing Mechanism 16
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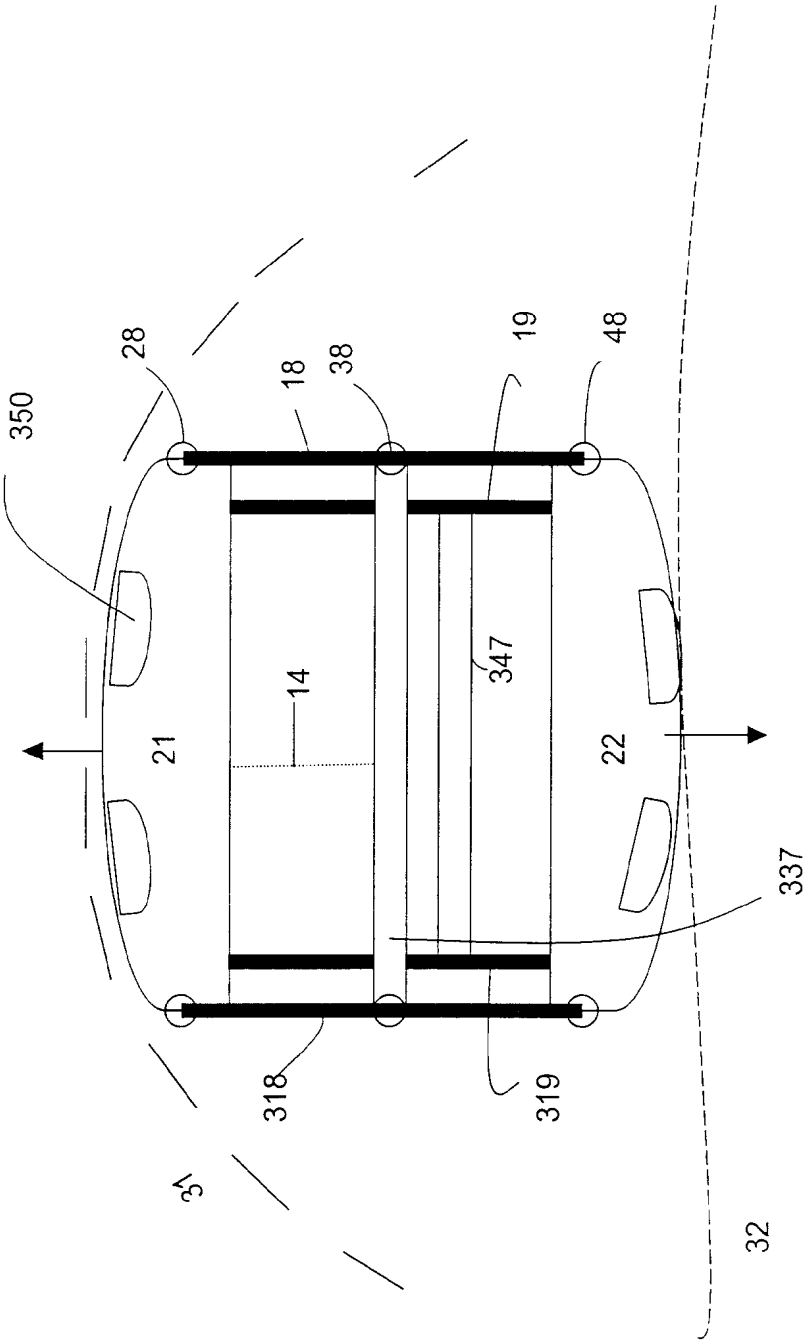
DEPLOYED CONFIGUATION

FIG. 3



INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 01/11156

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 235 966 A (JAMNER JAY) 17 August 1993 (1993-08-17) column 1, line 6 - line 12 column 3, line 12 - line 33 figures 1,2	1-10,13, 14,24-26
Y		12

Y	US 5 927 284 A (GRUENDEMAN PAUL F ET AL) 27 July 1999 (1999-07-27) abstract; figures 1,2B	12

X	US 3 667 474 A (LAPKIN KONSTANTIN VASILIEVICH ET AL) 6 June 1972 (1972-06-06) column 2, line 41 - line 61; figures 1,2	1-5,8, 10,13, 24-26

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
28 August 2001	06/09/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ducreau, F

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INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 01/11156

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	DE 44 12 171 A (KOSCHER STEFAN ;WUERTZ JOHANN (DE)) 12 October 1995 (1995-10-12) the whole document ---	1,24
A	US 5 662 676 A (KONINCKX PHILIPPE ROBERT) 2 September 1997 (1997-09-02) column 3, line 66 -column 4, line 16; figure 1 -----	1,24

2

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat .l Application No
PCT/US 01/11156

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